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January 12, 2005



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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on January 12, 2005.

Amy Yost

Amy Yost
Date of Signature: January 12, 2005

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: U.S. Patent Application Serial No. 09/874,103 for
SUBSTANTIALLY NON-TOXIC BIOLOGICALLY ACTIVE
MUCOSAL ADJUVANTS IN VERTEBRATE SUBJECTS
Our Ref. No. 297/102/2

Sir:

Please find enclosed in connection with the subject U.S. patent application the following documents:

1. Supplemental Information Disclosure Statement (2 pages);
2. Form PTO-1449 (1 page) in duplicate;
3. Copies of cited references (4 references); and
4. A return-receipt postcard to be returned to us with the U.S. Patent and Trademark Office filing stamp thereon.

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account No. 50-0426.

Respectfully submitted,

JENKINS, WILSON & TAYLOR, P.A.

Arles A. Taylor, Jr.
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AAT/acy
Enclosures
Customer No: 25297



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Amy Yost
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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Staats et al.

Group Art Unit: 1647

Serial No.: 09/874,103

Examiner: Landsman, Robert

Filed: June 5, 2001

Docket No. 180/102/2

Confirmation No.: 6817

For: SUBSTANTIALLY NON-TOXIC BIOLOGICALLY ACTIVE MUCOSAL
ADJUVANTS IN VERTEBRATE SUBJECTS

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with 37 C.F.R. 1.56, 1.97, and 1.98, applicants' undersigned attorney brings to the attention of the Patent and Trademark Office the documents listed on the attached Form PTO-1449. Copies of the references as well as Form PTO-1449 are attached hereto. This is not to be construed as a representation that a search has been made or that a reference is relevant merely because cited.

This information is being submitted subsequent to the mailing of a Final Action, but prior to the payment of the issue fee. Further, each item of information contained

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Appln. Serial No.: 09/874,103

herein was first cited in a communication from a foreign patent office in a related foreign application not more than three months prior to this filing.

Staats et al., *Journal of Immunology* **162**:6141-6147 (1999) is being submitted for completeness. However, applicants respectfully submit this document is not prior art as it was published after the priority date of the subject U.S. patent application.

Early passage of the subject application to issue is earnestly solicited.

The Commissioner is hereby authorized to charge the \$180.00 fee for the filing of this Information Disclosure Statement, and any other fees associated with the filing of this document, to Deposit Account No. 50-0426.

Respectfully submitted,

JENKINS, WILSON & TAYLOR, P.A.

Date:

1/12/2005

By:

Arles A. Taylor, Jr.
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AAT/acy

Enclosures

Customer No: 25297

FORM PTO-1449 U.S. Department of Commerce
Patent and Trademark Office

List of Documents Cited by Applicant



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|-----------------------|--------------|
| Application No.: | 09/874,103 |
| Filing Date: | June 5, 2001 |
| First Named Inventor: | Staats |
| Group: | 1647 |
| Examiner: | Landsman, R. |
| Attorney Docket No.: | 180/102/2 |

U.S. PATENT DOCUMENTS

| Examiner Initial | Cite No. | Document Number | Publication Date | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, where relevant passages or relevant figures appear |
|------------------|----------|-----------------|------------------|---|---|
| | | | | | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials | Cite No. | Document Number (country code, no., kind code (if known)) | Publication Date | Name of Patentee or Applicant | Pages, columns, lines where relevant passages appear | T |
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OTHER DOCUMENTS

| Examiner Initials | Cite No. | Include Author (in CAPITAL LETTERS), Title, Journal, Date, Pertinent Pages, Etc. | T |
|-------------------|----------|---|---|
| | 1. | European Search Report for European Patent Application No. 99951772.5 dated December 30, 2004. | |
| | 2. | STAATS ET AL., <i>IL -1 Is an Effective Adjuvant for Muscosal and Systemic Immune Responses When co administered with Protein Immunogens</i> , The American Association of Immunologists, 162 : 6141-6147 (1999). | |
| | 3. | HAZAMA ET AL., <i>Intranasal immunization against herpes simplex virus infection by using a recombiant glycoprotein D fused with immunomodulating proteins, the B subunit of Eschericha coli heat-labile enterotoxin and interleukin-2</i> , Immunology 78 : 643-649 (1993). | |
| | 4. | SASAKI, <i>Induction of Systemic and Mucosal Immune Responses to Human Immunodeficiency virus Ttpe 1 by a DNA Vaccine Formulated with QS-21 Saponin Adjuvant via Intramuscular and Intranasal Routes</i> , Journal of Virology, 72 (6) : 4931-4939 (1998). | |
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EXAMINER _____ DATE CONSIDERED _____

*Examiner Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.